

REMARKS

Claims 47-66 are now pending in the application. By this Paper, Claims 47, 48, 50, 52, 57-59, 61, 64, and 65 have been amended. The basis for the foregoing amendments can be found throughout the specification, claims, and drawings originally filed. No new matter has been added. The preceding amendments and the following remarks are believed to be fully responsive to the outstanding Office Action and are believed to place the application in condition for allowance. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

SPECIFICATION

Applicants have amended the Specification at Paragraph [0047] to correct a typographical error. No new matter has been added.

REJECTION UNDER 35 U.S.C. §§ 102 AND 103

Claims 47-66 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Duong et al. (U.S. Publication No. 2005/0049593).

Claims 47-66 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wagner et al. (U.S. Pub. No. 2001/0014807) in view of Nielson (U.S. Pat. No. 3,515,418).

These rejections are respectfully traversed.

At the outset, Applicants respectfully submit that the rejection of Claims 47-66 under 35 U.S.C. § 102(e) is moot, as the rejections under 35 U.S.C. § 102(e) have been

removed based on the Declaration filed under 35 U.S.C. § 1.131 on May 28, 2010. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

Applicants respectfully submit that the cited art of record fails to teach or suggest a bone fixation apparatus including an annular member moved between an expanded position and an unexpanded position by rotation of the annular member relative to a fastener shaft following insertion of the fastener shaft into a bone (Claim 47) or a bone fixation apparatus including an annular member movable between an unexpanded position and an expanded position independent from movement of a fastener shaft relative to a bone fixation plate (Claim 58). Further, Applicants respectfully submit that the cited art of record fails to teach or suggest a bone fixation apparatus including a circumferential groove formed in a fastener shaft, whereby the circumferential groove is spaced apart from each of a first end and a second end of the fastener shaft (Claim 65).

Wagner discloses a spinal plate system including a plate (10, 100), a ring (18, 118), and a bone screw (20, 120). See Wagner at Paragraph [0036] and Figure 4. Wagner discloses that an inner surface of the ring (18, 118) and an outer surface of a head (32, 125) of the screw (20, 120) are preferably tapered and shaped to mate with each other such that when the screw head (32, 125) engages the ring (18, 118), the ring (18, 118) expands outwardly from its inner surface to accommodate the increasing width of the screw head (32, 125). See Wagner at Paragraph [0052].

Based on the foregoing, Wagner discloses a bone screw (20, 120) that causes expansion of a ring (18, 118) **during** movement of the bone screw (20, 120) into the ring (18, 118). As such, Applicants respectfully submit that expansion of the ring (18, 118) is not **independent** from movement of the bone screw (20, 120) but, rather, is

directly caused by movement of the bone screw (20, 120). Further, because the ring (18, 118) expands outwardly due to insertion of the bone screw (20, 120) into the ring (18, 118), the ring (18, 118) is not rotated following insertion of the bone screw (20, 120) to thereby cause expansion of the ring (18, 118). In fact, Applicants respectfully submit that Wagner is completely silent with respect to rotating the ring (18, 118) relative to the bone screw (20, 120) to position the ring (18, 118) into an expanded position or otherwise.

With respect to Claim 65, Applicants respectfully submit that the cited art of record fails to teach or suggest a circumferential groove formed in a fastener shaft that carries an annular member. While Nielsen discloses a cam portion (24) that is recessed from a cylindrical body portion (22), the cam (24) does not constitute a circumferential groove and, further, is not spaced apart from an end of the device of Nielsen but, rather, extends from the cylindrical body portion (22) to a distal end of the device. See Nielsen at Figure 3.

While Applicants have amended independent Claims 47, 58, and 65 to further prosecution, Applicants respectfully submit that the combination of Wagner and Nielsen is improper, as Nielsen is non-analogous art.

Generally speaking, there are two criteria for determining whether prior art is analogous. The art must either be from the same field of endeavor or, if not within the same field of endeavor, must be “reasonably pertinent” to the particular problem with which the inventor is involved. See *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). Applicants note that while the Supreme Court recently held that “familiar items may have obvious uses beyond their primary purposes” in *KSR Int’l Co. v. Teleflex, Inc.*, the

Supreme Court did not abolish the foregoing criteria for determining whether prior art is analogous. See *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1742 (2007). In fact, Applicants note that the Federal Circuit, as well as the Board of Patent Appeals and Interferences (BPAI), have applied the foregoing criteria for determining whether prior art is analogous following the *KSR* decision. See, for example, *In re Icon Health & Fitness, Inc.*, 496 F.3d 1374 (Fed. Cir. 2007) and *Ex Parte Ralph Kurt*, Appeal 2007-4172, BPAI (2007). In determining whether a reference is “reasonably pertinent,” the purpose of both the invention and the prior art are important, as well as determining whether the matter with which the art deals would have “commended itself to an inventor’s attention” in considering the inventor’s problem. See *Clay*, 966 F.2d at 659.

Applicants respectfully submit that Nielsen is not within the field of endeavor of the subject application, as the subject application is directed to a bone fixation device and the device of Nielsen is directed to a locking mechanism for a telescoping assembly. Applicants further submit that the device of Nielsen is not “reasonably pertinent” to the present application, as the matter with which it deals (i.e., a temporary locking mechanism for a telescoping assembly) would not have “commended itself to an inventor’s attention” in designing a bone fixation device.

Applicants submit that the purpose of the device of Nielsen is to temporarily lock a tube (12) relative to another tube (11) to allow the device of Nielsen to be selectively moved between a collapsed state and an extended state. See *Nielsen* at the Abstract and Figure 2. In contrast, the device of the subject patent application includes a fastener shaft that is intended to attach a bone fixation plate to a bone in a somewhat permanent fashion. Given the foregoing, Applicants respectfully submit that one of

ordinary skill in the art—when designing a bone fixation device that permanently attaches a bone fixation plate to a bone—would not look to a system that temporarily attaches a first cylindrical tube to a second cylindrical tube to allow the second cylindrical tube to telescope relative to the first cylindrical tube. Further, Applicants note that the locking mechanism of Nielsen is directed to fixing telescoping tubes to one another and that a person of skill in the art designing a bone fixation apparatus having a plate and a fastener shaft (neither of which are tubes) would not look to art joining a pair of cylindrical structures in doing so. Based on the foregoing, Applicants respectfully submit that the device of Nielsen is not reasonably pertinent to the device of the subject patent application and, as such, respectfully submit that Nielsen is non-analogous art.

In light of the foregoing, Applicants respectfully submit that independent Claims 47, 58, and 65, as well as Claims 48-57, 59-64, and 66, respectively dependent therefrom, are in condition for allowance. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner

believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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